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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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1601 MARKET STREET  
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EXAMINER

DAVIS, M

ART UNIT

PAPER NUMBER

1642

DATE MAILED:

07/05/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

09/519,665

Applicant(s)

Hinrichs, S H

Examiner

Minh-Tam Davis

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 6, 2000.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-55 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 1-55 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892) 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) ☐ Notice of Informal Patent Application (PTO-152)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 20) ☐ Other:

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## **DETAILED ACTION**

### ***Election/Restriction***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Group I. Claims 1-5, 8, 17-22, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor, wherein the transcriptional factor is a b-ZIP transcription factor, classified in class 424, subclass 130.1.

Group II. Claims 1-4, 6, 8, 17-22, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor, wherein the transcriptional factor is a helix-loop-helix protein, classified in class 424, subclass 130.1.

Group III. Claims 1-4, 7, 8, 17-22, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor, wherein the transcriptional factor is a zinc finger protein, classified in class 424, subclass 130.1.

Group IV. Claims 1-4, 9-14, 17-22, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor, wherein the transcriptional factor is fusion protein EWS/ATF1, classified in class 424, subclass 130.1.

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Group V. Claims 1-4, 9-13, 15, 17-22, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor, wherein the transcriptional factor is fusion protein EWS/FLI, classified in class 424, subclass 130.1.

Group VI. Claims 1-4, 9-13, 16, 17-22, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor, wherein the transcriptional factor is fusion protein PAX/FKHR, classified in class 424, subclass 130.1.

Group VII. Claim 23, drawn to a method for screening modulators of b-ZIP transcription factor, classified in class 435, subclass 7.1.

Group VIII. Claim 23, drawn to a method for screening modulators of a transcription factor which is a helix-loop-helix protein, classified in class 435, subclass 7.1.

Group IX. Claim 23, drawn to a method for screening modulators of a transcription factor which is a zinc finger protein, classified in class 435, subclass 7.1.

Group X. Claim 23, drawn to a method for screening modulators of a transcription factor which is EWS/ATF1, classified in class 435, subclass 7.1.

Group XI. Claim 23, drawn to a method for screening modulators of a transcription factor which is EWS/FLI, classified in class 435, subclass 7.1.

Group XII. Claim 23, drawn to a method for screening modulators of a transcription factor which is PAX/FKHR, classified in class 435, subclass 7.1.

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Group XIII. Claims 24-32, drawn to a method for treating an individual having a transcriptional factor-mediated disease, comprising exposing a B-ZIP transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor, classified in class 424, subclass 130.1.

Group XIV. Claims 24-32, drawn to a method for treating an individual having a transcriptional factor-mediated disease, comprising exposing a transcriptional factor which is a helix-loop-helix protein to an inhibitory agent, which binds to a linker domain of said transcriptional factor, classified in class 424, subclass 130.1.

Group XV. Claims 24-32, drawn to a method for treating an individual having a transcriptional factor-mediated disease, comprising exposing a transcriptional factor which is a zinc finger protein to an inhibitory agent, which binds to a linker domain of said transcriptional factor, classified in class 424, subclass 130.1.

Group XVI. Claims 24-32, drawn to a method for treating an individual having a transcriptional factor-mediated disease, comprising exposing a transcriptional factor which is fusion protein EWS/ATF1 to an inhibitory agent, which binds to a linker domain of said transcriptional factor, classified in class 424, subclass 130.1.

Group XVII. Claims 24-32, drawn to a method for treating an individual having a transcriptional factor-mediated disease, comprising exposing a transcriptional factor which is fusion protein EWS/FLI to an inhibitory agent, which binds to a linker domain of said transcriptional factor, classified in class 424, subclass 130.1.

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Group XVIII. Claims 24-32, drawn to a method for treating an individual having a transcriptional factor-mediated disease, comprising exposing a transcriptional factor which is fusion protein PAX/FKHR to an inhibitory agent, which binds to a linker domain of said transcriptional factor, classified in class 424, subclass 130.1.

Group XIX. Claims 33-45, drawn to an inhibitory agent, which binds to a linker domain of a b-ZIP transcriptional factor, classified in class 530, subclass 387.1.

Group XX. Claims 33-45, drawn to an inhibitory agent, which binds to a linker domain of a transcriptional factor, which is a helix-loop-helix protein, classified in class 530, subclass 387.1.

Group XXI. Claims 33-45, drawn to an inhibitory agent, which binds to a linker domain of a transcriptional factor, which is a zinc finger protein, classified in class 530, subclass 387.1.

Group XXII. Claims 33-45, drawn to an inhibitory agent, which binds to a linker domain of a transcriptional factor, which is fusion protein EWS/ATF1, classified in class 530, subclass 387.1.

Group XXIII. Claims 33-45, drawn to an inhibitory agent, which binds to a linker domain of a transcriptional factor, which is fusion protein EWS/FLI, classified in class 530, subclass 387.1.

Group XXIV. Claims 33-45, drawn to an inhibitory agent, which binds to a linker domain of a transcriptional factor, which is fusion protein PAX/FKHR, classified in class 530, subclass 387.1.

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Group XXV. Claims 46-48, drawn to a method for modulating transcriptional factor-mediated replication of viruses, comprising exposing a b-ZIP transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor, classified in class 424, subclass 130.1.

Group XXVI. Claims 46-48, drawn to a method for modulating transcriptional factor-mediated replication of viruses, comprising exposing a transcriptional factor, which is a helix-loop-helix protein, to an inhibitory agent, which binds to a linker domain of said transcriptional factor, classified in class 424, subclass 130.1.

Group XXVII. Claims 46-48, drawn to a method for modulating transcriptional factor-mediated replication of viruses, comprising exposing a transcriptional factor, which is a zinc finger protein, to an inhibitory agent, which binds to a linker domain of said transcriptional factor, classified in class 424, subclass 130.1.

Group XXVIII. Claims 46-48, drawn to a method for modulating transcriptional factor-mediated replication of viruses, comprising exposing a transcriptional factor, which is fusion protein EWS/ATF1, to an inhibitory agent, which binds to a linker domain of said transcriptional factor, classified in class 424, subclass 130.1.

Group XXIX. Claims 46-48, drawn to a method for modulating transcriptional factor-mediated replication of viruses, comprising exposing a transcriptional factor, which is fusion protein EWS/FLI, to an inhibitory agent, which binds to a linker domain of said transcriptional factor, classified in class 424, subclass 130.1.

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Group XXX. Claims 46-48, drawn to a method for modulating transcriptional factor-mediated replication of viruses, comprising exposing a transcriptional factor, which is fusion protein PAX/FKHR, to an inhibitory agent, which binds to a linker domain of said transcriptional factor, classified in class 424, subclass 130.1.

Group XXXI. Claims 49-55, drawn to Claims 1-5, 8, 17-22, drawn to a method for modulating transcriptional factor-mediated cellular proliferation, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor, wherein the transcriptional factor is a b-ZIP transcription factor, classified in class 424, subclass 130.1.

Group XXXII. Claims 49-55, drawn to a method for modulating transcriptional factor-mediated cellular proliferation, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor, wherein the transcriptional factor is a helix-loop-helix, classified in class 424, subclass 130.1.

Group XXXIII. Claims 49-55, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor, wherein the transcriptional factor is a zinc finger protein, classified in class 424, subclass 130.1.

Group XXXIV. Claims 49-55, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent,



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which binds to a linker domain of said transcriptional factor, wherein the transcriptional factor is fusion protein EWS/ATF1, classified in class 424, subclass 130.1.

Group XXXV. Claims 49-55, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor, wherein the transcriptional factor is fusion protein EWS/FLI, classified in class 424, subclass 130.1.

Group XXXVI. Claims 49-55, drawn to a method for modulating transcriptional factor-mediated gene expression, comprising exposing said transcriptional factor to an inhibitory agent, which binds to a linker domain of said transcriptional factor, wherein the transcriptional factor is fusion protein PAX/FKHR, classified in class 424, subclass 130.1.

In addition, upon the election of any of groups I-XXXVI, further election of the following patentably distinct species of the claimed invention is required:

1) Antibody, or a subcomponent of an antibody, 2) a peptide mimetic, and 3) a non-peptide mimetic.

Upon the election of any of groups I, VII, XIII, XIX, XXV and XXXI, further election of the following patentably distinct species of the claimed invention is required:

One member only of the b-ZIP transcriptional factor family, e.g. CREB, ATF1, GCN4, AP-1 components, fos or jun, as disclosed on pages 3 and 6 of the specification.

Upon the election of any of groups I-VI, XIII-XVIII, further election of the following patentably distinct species of the claimed invention is required:

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Neoplasia or infectious disease.

Upon election of the species neoplasia, further election of the following patentably distinct species of the claimed invention is required:

Leukemia, lymphomas, and sarcomas.

2. The inventions are distinct, each from each other because of the following reasons:

Inventions (I-XVIII, XXV-XXXVI) and (XIX-XXIV) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h)). In this instant case an antibody could be used for immunoassay, for purification of its antigen, and for detection of diseases.

The methods of groups (I-XVIII, XXV-XXXVI) are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success. The reagent antibodies are distinct because each antibody binds to a different epitope, having different structure. Further, modulation of a gene expression or a cell proliferation does not necessarily mean that a disease is treated. Moreover, the properties of virus is different than those of mammalian or bacterial cells.

The species antibody, peptide mimetics and non-peptide mimetics are distinct because they are structurally distinct.

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The species members of the b-ZIP transcriptional factor family, e.g. CREB, ATF1, GCN4, AP-1 components, fos or jun, are distinct because they are structurally distinct.

The species neoplasia and infectious diseases are distinct because they are different diseases with different etiology.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art as shown by their different classification, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the

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examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

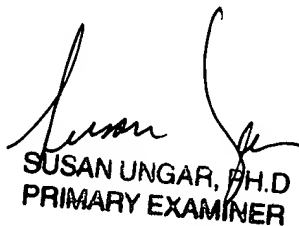
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

May 15, 2001

  
SUSAN UNGAR, PH.D  
PRIMARY EXAMINER